DEC 2 3 2005

Ortho-Clinical Diagnostics
a Johnson-Johnson company
100 Indigo Creek Drive
Rochester, New York 14626-5101

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K052819

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4253
Contact Person: Darlene Phillips

2. **Preparation Date**

October 3, 2005

3. **Device name**

Trade or Proprietary Names:
VITROS Chemistry Products AAT Reagent
VITROS Chemistry Products Calibrator Kit 99
VITROS Chemistry Products AAT Performance Verifiers I, II & III

Common Names:
Alpha-1-antitrypsin (AAT) assay and controls

Classification Names:
Alpha-1-antitrypsin immunological test system (866.5130) Class II
Calibrator (862.1150) Class II
Quality Control material (assayed and unassayed) (862.1660) Class I (general controls). Since these devices (AAT Performance Verifiers I, II & III) are assayed controls, they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

Continued on next page

4. Predicate Devices

The VITROS Chemistry Products AAT assay is substantially equivalent to the IMMAGE® Immunochemistry Systems AAT assay.

The VITROS Chemistry Products AAT Performance Verifiers are substantially equivalent to the previously cleared VITROS Chemistry Products Protein Performance Verifiers.

5. Device description

The VITROS Chemistry Products AAT Reagent is used in conjunction with the VITROS Chemistry Products Calibrator Kit 99 and VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) on VITROS 5,1 FS Chemistry Systems for the quantitative measurement of α_1-antitrypsin (AAT) in human serum.

The VITROS AAT Reagent is a dual chambered package containing ready-to-use liquid reagents. Samples, calibrators and controls are automatically diluted in saline from VITROS FS Diluent Pack 2 and mixed with Reagent 1 containing a polymer. Addition of antisera specific for human α_1-antitrypsin (Reagent 2) produces an immunochemical reaction yielding antigen/antibody complexes. The light scattering properties of the antigen/antibody complexes increase solution turbidity proportional to α_1-antitrypsin concentration in the sample. The turbidity is measured spectrophotometrically at 340 nm. Once a calibration has been performed for each reagent lot, the α_1-antitrypsin concentration in each unknown sample can be determined using the stored calibration curve and the measured absorbance obtained in the assay of the sample.

The VITROS Chemistry Products Calibrator Kit 99 are prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added. These standards are used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of α_1-antitrypsin (AAT).

The VITROS Chemistry Products AAT Performance Verifiers I, II and III are prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added. These are assayed controls used to monitor performance of VITROS AAT Reagent on VITROS 5,1 FS Chemistry Systems.

Continued on next page

The VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) is a common reagent that is used by multiple assays on the VITROS 5,1 FS System. This is a dual chambered package containing two ready-to-use liquid diluents. Diluent 1 is prepared from processed water to which inorganic salt has been added. Diluent 2 is prepared from processed water to which bovine serum albumin, inorganic salts and preservatives have been added.

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS Chemistry Products MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS System was cleared for market by 510(k) premarket notification (K031924).

6. Device intended uses

VITROS Chemistry Products AAT Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products AAT Reagent is used to quantitatively measure α_1-antitrypsin concentration in human serum.

VITROS Chemistry Products Calibrator Kit 99: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of α_1-antitrypsin (AAT).

VITROS Chemistry Products AAT Performance Verifiers I, II & III: For *in vitro* diagnostic use only. VITROS Chemistry Products AAT Performance Verifiers are assayed controls used to monitor performance of VITROS AAT Reagents on VITROS 5,1 FS Chemistry Systems.

7. Comparison to predicate devices:

The VITROS Chemistry Products AAT Reagent and VITROS Chemistry Products Calibrator Kit 99 are substantially equivalent to the IMMAGE® Immunochemistry Systems AAT Reagent (K964766) and Calibrator 2 (K973932) (predicate devices) which were cleared by the FDA for IVD use.
Passing & Bablock linear regression analysis demonstrated the following relationship:

$$y = 0.93x + 2.06 \text{ mg/dL}$$

where y = results obtained using the VITROS Chemistry Products AAT assay and x = results obtained with the commercially available system IMMAGE® Immunochemistry Systems AAT assay in conventional units.

The VITROS Chemistry Products AAT Performance Verifiers I, II & III are substantially equivalent to the VITROS Chemistry Products Protein Performance Verifiers I, II & III (K042477) (predicate device) which was cleared by the FDA for IVD use.

Continued on next page

In addition to correlation studies, bench testing was performed to determine assay precision, linearity, specificity, expected values, limit of detection, dilution and specimen matrix of the VITROS AAT assay.

Table 1 Similarities and differences of the assays performed using the VITROS AAT assay and the IMMAGE® AAT assay.

Device Similarities		
Indications for Use	For *in vitro* diagnostic use. Quantitative measurement of α_1-antitrypsin in human samples. The measurement of α_1-antitrypsin in serum aids in the diagnosis of α_1-antitrypsin deficiency.	
Antibody source	Ovine (Goat)	
Instrumentation	Clinical chemistry analyzer	
Calibrator matrix	Human serum	
Differences		
Device Characteristic	**VITROS AAT assay (New device)**	**IMMAGE AAT assay (Predicate device)**
Sample Type	Serum	Serum
Reportable Range	30.00 – 450.00 mg/dL	10 – 3,600 mg/dL
Calibrator levels	Five levels	Single level
Calibrator format	Liquid	Lyophilized
Method	Immunoturbidimetric	Nephelometric

Table 2 Similarities and differences of the device characteristics between the VITROS AAT Performance Verifiers I, II & III with the predicate device VITROS Chemistry Products Protein Performance Verifiers I, II & III.

Device Similarities		
Indications for Use	For *in vitro* diagnostic use. Assayed controls used to monitor the performance on VITROS Chemistry Systems.	
Matrix	The performance verifiers are prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.	
Format	Liquid	
Number of levels	Three	
Differences		
Device Characteristic	**VITROS AAT Performance Verifiers (New Device)**	**VITROS Protein Performance Verifiers (Predicate Device)**
Analytes Reported	α_1-Antitrypsin (AAT)	Several including complement C3 (C3), complement C4 (C4), IgA, IgG, IgM and transferrin.

Continued on next page

8. Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products AAT Reagent, VITROS Chemistry Products Calibrator Kit 99, and the VITROS Chemistry Products AAT Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ortho-Clinical Diagnostics, Inc.
c/o Ms. Darlene J. Phillips
Regulatory Affairs Associate
100 Indigo Creek Dr.
Rochester, NY 14626-5101

DEC 2 3 2005

Re: k052819
Trade/Device Name: VITROS Chemistry Products AAT Reagent
VITROS Chemistry Products Calibrator Kit 99
VITROS Chemistry Products AAT Performance Verifiers I, II and III
Regulation Number: 21 CFR 866.5130
Regulation Name: Alpha-1 antitrypsin immunological test system
Regulatory Class: Class II
Product Code: DEM, JIX, JJX
Dated: October 3, 2005
Received: October 25, 2005

Dear Ms. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

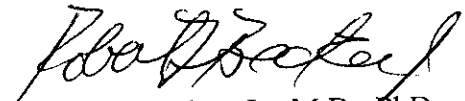
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0131. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Robert L. Becker, Jr., M.D., PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052819

Device Name: VITROS Chemistry Products AAT Reagent
VITROS Chemistry Products Calibrator Kit 99
VITROS Chemistry Products AAT Performance Verifiers I, II, and III

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products AAT Reagent is used to quantitatively measure α_1-antitrypsin concentration in human serum. The measurement of α_1-antitrypsin in serum aids in the diagnosis of cirrhosis of the liver and pulmonary emphysema.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of α_1-antitrypsin (AAT).

For *in vitro* diagnostic use only. VITROS Chemistry Products AAT Performance Verifiers are assayed controls used to monitor performance of VITROS AAT Reagents on VITROS 5,1 FS Chemistry Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mana Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K052819